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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,910	11/28/2000	Hugh J. Pasika	7414.0025	8658

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FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20006

EXAMINER
MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/05/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,910	Applicant(s) PASIKA ET AL.	
	Examiner Channing S. Mahatan	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1, 2, 4, 5, 7-13, 16-24, 26, 27, and 29-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,14,15,25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 11, filed 22 August 2002, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 3, 6, 14, 15, 25, and 28. Claims 1, 2, 4, 5, 7-13, 16-24, 26, 27, and 29-33 remain withdrawn.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in

molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 3, 6, 14, 15, 25, and 28 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for "making an allele call", does not reasonably provide enablement for "making a correct allele call". Applicants' support for "making a correct allele call" (page 14, line7 to page 15, line 9 of the Specification) is absent; failing to indicate that the allele call made is "correct". The below explanation not only provides for the lack of enablement rejection, but additionally a scope of enablement rejection regarding the step of "making an allele call", which is not commensurate in scope with the specification. The Envelope Caller assesses the complexity of the signal from the nucleic acid sequencer prior to "making an allele call". If the signal's complexity is below a threshold the Envelope Caller makes the call (page 13, lines 5-7 of the Specification) and this call "stands an excellent chance of being correct" (page 13, lines 8-9 of the Specification), though this does not indicate that the call is indeed "correct". Whether or not the Envelope Caller should "make an allele call" requires that the algorithm first to determine if three panels exist (page 14, lines 7-8 of the Specification), wherein the original signal is divided into panels at each minimum (page 14, lines 4-5). The energy level for each panel (complexity) is computed by summing the square of each element in the panel. The energy levels of the three panels must be of sufficiently low complexity for the Envelope Caller to operate/call; as defined threshold for the complexity is when: E2 is greater than 20% of E1 and E3 is no more that 7% of E2 (page 15, lines1-5 of the

Specification). It should be noted that the specification recites "If, at least three panels exist ...", unclear is the threshold determination if more than three panels exist. Additionally, none of the above steps or elements are limitations of the claims, and the specification does not provide guidance as to other types of analysis or ways to perform these steps.

Further, claims 3 (line 4), 14 (line 5), and 25 (line 5) are not commensurate in scope with the specification with regard to the instantly claimed step of "determining a complexity of a signal". As stated above, the energy level for each panel (complexity) is computed by summing the square of each element in the panel. No other methods of "determining a complexity of a signal" are disclosed and the specification provides no guidance as to other methods for "determining a complexity of a signal" that could be used (page 14, lines 10-11). Applicants assert that one skilled in the art would know the meaning of the term "complexity" particularly pointing to page 14, line7 to page 15, line 9 of the specification, however, as disclosed complexity is simply the energy level of each panel, and fails to provide additional meaning beyond energy level for each panel. There does not appear to be an art understood meaning for the term "complexity" such that one would know other ways of using this information in the claimed method.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. § 122(b). Therefore, this application is examined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

Claims 3, 6, 14, 15, 25, and 28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Perlin (U.S. Patent No. 5,580,728). This rejection is maintained with respect to claims 3, 6, 14, 15, 25, and 28. As recited in the previous office action Paper No. 9, mailed 22 April 2002.

Applicants argue that Perlin (U.S. Patent No. 5,580,728) fails to teach making a correct allele call based on the determined complexity for the signal, as recited in claims 13, 14, and 25, which is found unpersuasive. The method, system, and computer readable medium taught by Perlin has the goal of "making a correct allele call based on the determined complexity of the signal" (Column 12, lines 26-28). The term "complexity" is sufficiently broad to include the analysis used by Perlin (even with respect to claims 6, 15, and 28), wherein the instant claims fail to indicate the limitations of "complexity" as recited in the disclosure (Refer to the above 112 1st

Paragraph Rejection and page 14, line 7 to page 15, line 9 of the Specification). Therefore, the arguments are non-persuasive to overcome the rejection.

Claims 3, 6, 14, 15, 25, and 28 are rejected under 35 U.S.C. § 102 (e) as being anticipated by Hiller et al. (U.S. Patent No. 6,274,317 B1). This rejection is maintained with respect to claims 3, 6, 14, 15, 25, and 28. As recited in the previous office action Paper No. 9, mailed 22 April 2002.

Applicants argue that Hiller et al. (U.S. Patent No. 6,274,317 B1) fails to teach making a correct allele call based on the determined complexity for the signal, as recited in claims 13, 14, and 25, which is found unpersuasive. The method, system, and computer readable medium taught by Hillier et al. has the goal of "making a correct allele call based on the determined complexity of the signal" (Column 9, lines 24-64). Again, the term "complexity" is sufficiently broad to include the analysis used by Hillier (even with respect to claims 6, 15, and 28), wherein the instant claims fail to indicate the limitations of "complexity" as recited in the disclosure (Refer to the above 112 1st Paragraph Rejection and page 14, line 7 to page 15, line 9 of the Specification). Therefore, the arguments are non-persuasive to overcome the rejection.

OBJECTION TO DISCLOSURE

The objection to Table 1 (page 14) with regard to the requirement that the line spacing be either double-spaced or at least 1 ½ spaced and not single spaced as in Table 1 is withdrawn.

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: November 1, 2002

Examiner Initials: CSM

Marianne P. Allen

AU1631